

REMARKS

Claims 1-6, 8-24 and 28-41 are pending in the instant application. Claims 5, 6, 8-22 and 41 have been withdrawn from consideration by the Examiner as being directed to a non-elected invention. Applicants have canceled claims 5, 6, 8-21 and 32 without prejudice or disclaimer to the subject matter claimed therein. Claims 1, 22, 23 and 40 have been amended. New claim 42 has been added.

Applicants respectfully submit that support for the amendments to claims 1, 22, and 23 can be found, for example, in Paragraphs [0042], [0046] and [0059] of the specification as originally filed.

Claim Rejections 35 USC §112

Claims 3 and 29 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Action states that "DLPLA" appears to be a typographical error or is not defined in the specification.

Applicants respectfully traverse this rejection. Applicants respectfully submit that "DLPLA" is fully supported by the specification as filed, specifically in Paragraph [0031], for example. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claim Rejections 35 USC §103

Claims 1-4, 23-24 and 28-40 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0146541 A1 to Nakamura et al. (herein after referred to as "Nakamura") in view of U.S. Patent Application Publication US 2001/0004693 A1 to Burkhead et al. (hereinafter referred to as "Burkhead"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that neither Nakamura nor Burkhead, whether taken individually or in permissible combination, discloses or suggests the claimed invention.

The Action states that Nakamura discloses a bone connecting device having a head and shank portion, wherein the shank portion is molecularly oriented and a head portion which is heated and reshaped to have a wider cross-section than the shank portion, wherein the shank portion has regions of lesser and greater orientation. The Action admits that the reference fails to explicitly disclose a device in which the head has less orientation than the shank portion.

The Action goes on to state that Burkhead discloses that it is well known in the art to have the region of reinforcement resulting from molecular orientation concentrated in the shank portion of a bone fixing device and leaving the head portion of a bone fixing device with less reinforcement (i.e., molecular orientation) than the shank portion (referring to Figs. 4A-4D).

The Action concludes that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make an implantable article having varying regions of self-reinforcement via molecular orientation in order to selectively increase the mechanical properties in high stress regions.

The Action states that it has reason to believe that the reheating and forming operations used in Nakamura to reshape the head portion would at least partially disrupt the molecular orientation in the head portion, thereby producing a head portion with less molecular orientation than the shank portion. In response, Applicants respectfully submit that, the Nakamura implant neither discloses nor suggests the claimed implant. Specifically, and assuming *arguendo* that the Action is correct that the deformation to produce the head **reduces** the amount of molecular orientation, the polymer molecules in the head region would no longer be oriented substantially in the direction of the longitudinal axis. To the extent the polymer molecules were still at least somewhat oriented, they would be oriented in directions perpendicular to the axis. This would seem to be analogous to pressing axially on the end of a bundle of soft, cooked spaghetti. Except for the region at or very near the location where the bundle is grasped, the bundle will buckle and the spaghetti strands will splay out in directions away from the axial direction. The final product created by Nakamura would lack the strength characteristics of a device where the polymer molecules are oriented throughout the device and along the axis of the device.

Applicants respectfully submit that the Burkhead reference fails to remedy the deficiency. Specifically, Applicants respectfully submit that Burkhead neither discloses nor suggests differences or variations in the molecular orientation of his polymer in different regions of his implant fastener device. Applicants traverse the characterization of Figs 4A-4D of Burkhead as allegedly showing regions of reinforcement resulting from molecular orientation, let alone that such orientation is concentrated in the shank portion. Applicants submit that Fig. 4A is merely to show that the reinforcement should be aligned parallel to the shank of the fastener. Fig. 4A is not meant to show that the head portion contains less reinforcement or less-aligned reinforcement. Further, Fig. 4D shows a spiral arrangement of the reinforcement. Seemingly, this would be of the fibrous reinforcement, as it is unclear to Applicants how to achieve spiral going in two different directions with molecular orientation. So, this raises doubt as to whether the lines in Figs 4A-4D are lines of molecular orientation. Instead, Applicants respectfully submit that they are lines depicting fibrous reinforcement. The dual spiral orientation of Fig. 4D is then explained.

Burkhead states that high speed flow and pressure of his polymer melt can give rise to molecular orientation upon cooling (Paragraph [0024]). This is unclear to Applicants, as it is their understanding that such orientation develops only when the polymer is in the glass transition range, and as a melt, Burkhead's polymer would be above this temperature range. Regardless, there is no suggestion that the polymer orientation of Burkhead is anything except uniform.

Besides, Burkhead neither discloses nor suggests the implant of independent claims 1 and 23 and their dependents, having molecular orientation aligned with the longitudinal axis of the device, as the device of Burkhead does not have a longitudinal axis, as it does not have an axis. It does not have an axis of symmetry.

Applicants furthermore respectfully submit that dependent claim 24 is independently patentable over Nakamura and/or Burkhead. In particular, dependent claim 24 is directed to machining the molded implant to a finished product. Nakamura teaches away from machining. See his Paragraphs [0005] and [0007].

Accordingly, Applicants respectfully request that this rejection be withdrawn.

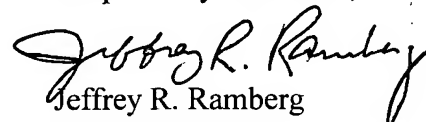
CONCLUSION

The difference between the Nakamura device and that of the claimed invention can be seen as follows, even if both devices start out with at least partially aligned polymer molecules, and even if the initial alignment is substantially parallel to the longitudinal axis of the device: In the claimed invention, the shank portion of an elongated fastener such as a screw undergoes more deformation than the head. In Nakamura, the head undergoes more deformation than the shank portion of the device, and is deformed in a way such that polymer material in the head flows in directions other than the longitudinal axis direction, e.g., in a radial direction. At a minimum, any remaining orientation of polymer molecules in the Nakamura device will be in directions other than in the longitudinal direction.

In view of the above remarks, Applicants respectfully submit that the present application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 1-4, 23, 24, 28-31, 33-40 and 42.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,


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